

Site: Administration of Porcine Spinal Cord Cells (SCIR)
Document Number: BR0055-0

Revision: 00
Effective Date APR 12 2001

Patient Number: SRL-05

Date: 9/25/01

Received on: 9/25/01

Product Lot Number: SCIRC09

Time of Arrival of Cells: 4:40 PM

1. The site of damage within the spinal cord will be localized by MRI. A laminectomy will be performed at a location one segment above or below the site of damage. With the spinal cord revealed, the dura will be opened and a needle inserted into the spinal cord to deliver the cells.

NOTE: All draws of fluid must be done very slowly to prevent bubble formation.

2. Gently resuspend (do not shake) the cells for transplant (which have collected into a pellet) by repetitively rotating the vial 90° to the right and to the left until the pellet of cells has dislodged and a uniformly cloudy suspension is achieved.
3. Place the tip of the needle in the cryovial containing the cell suspension for transplant and draw up a maximum of 20 µl.
4. Cells will be delivered to the selected site of the spinal cord bilaterally, and along the entire segment. The distance between tracts along the segment will be approximately 1 – 3 mm. Effort should be made to evenly space the bilateral distance between injection tracts. The exact number of injections will be dependent on the segment of the cord being transplanted because of the variation in the size of segments along the spinal cord.
5. The cells must be injected slowly into the spinal cord to avoid cells being forced back along the needle tract and out of the target site. The volume of cells to be injected at each site is a maximum of 20 microliters, which is equal to 2 million cells. Once the target site is selected, the needle is inserted approximately 3 – 7 mm deep into the spinal cord targeting the ventral horn gray matter. Cells are to be injected at a rate of approximately 4 µl per minute until 10—20 µl cells are injected.
6. After the final injection of cells at a target site, the needle/syringe will be held in place for 2-5 minutes. This wait period will allow the cells and injection solution to equilibrate with surrounding tissue to minimize the chance of leakage of cells along the needle tract.
7. Remove the needle / syringe from spinal cord.

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APPENDIX F

Title: Administration of Porcine Spinal Cord Cells (SCIR)
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APR 12 2001

8. Record the following information on the attached form:

- Injection site number
- Start time (cannula inserted)
- Stop time (removal of cannula)
- Distance between deposits
- Number of deposits

9. Repeat steps for each of the remaining injection tracts.

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le: Administration of Porcine Spinal Cord Cells (SCIR)
Document Number: BR0055-0

Revision: 00
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atient Number: LDS-04

Date: 7/10/01

Received on: 7/10/01

Product Lot Number: SC12008

Time of Arrival of Cells: 7:30 AM

1. The site of damage within the spinal cord will be localized by MRI. A laminectomy will be performed at a location one segment above or below the site of damage. With the spinal cord revealed, the dura will be opened and a needle inserted into the spinal cord to deliver the cells.

NOTE: All draws of fluid must be done very slowly to prevent bubble formation.

2. Gently resuspend (do not shake) the cells for transplant (which have collected into a pellet) by repetitively rotating the vial 90° to the right and to the left until the pellet of cells has dislodged and a uniformly cloudy suspension is achieved.
3. Place the tip of the needle in the cryovial containing the cell suspension for transplant and draw up a maximum of 20 µl.
4. Cells will be delivered to the selected site of the spinal cord bilaterally, and along the entire segment. The distance between tracts along the segment will be approximately 1 – 3 mm. Effort should be made to evenly space the bilateral distance between injection tracts. The exact number of injections will be dependent on the segment of the cord being transplanted because of the variation in the size of segments along the spinal cord.
5. The cells must be injected slowly into the spinal cord to avoid cells being forced back along the needle tract and out of the target site. The volume of cells to be injected at each site is a maximum of 20 microliters, which is equal to 2 million cells. Once the target site is selected, the needle is inserted approximately 3 – 7 mm deep into the spinal cord targeting the ventral horn gray matter. Cells are to be injected at a rate of approximately 4 µl per minute until 10—20 µl cells are injected.
6. After the final injection of cells at a target site, the needle/syringe will be held in place for 2-5 minutes. This wait period will allow the cells and injection solution to equilibrate with surrounding tissue to minimize the chance of leakage of cells along the needle tract.
7. Remove the needle / syringe from spinal cord.

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Revision: 00
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Patient Number: WDS-03

Date: 4/12/01

Received on: 6/12/01

Product Lot Number: Scir007

Time of Arrival of Cells: 8:00 AM

1. The site of damage within the spinal cord will be localized by MRI. A laminectomy will be performed at a location one segment above or below the site of damage. With the spinal cord revealed, the dura will be opened and a needle inserted into the spinal cord to deliver the cells.

NOTE: All draws of fluid must be done very slowly to prevent bubble formation.

2. Gently resuspend (do not shake) the cells for transplant (which have collected into a pellet) by repetitively rotating the vial 90° to the right and to the left until the pellet of cells has dislodged and a uniformly cloudy suspension is achieved.
3. Place the tip of the needle in the cryovial containing the cell suspension for transplant and draw up a maximum of 20 µl.
4. Cells will be delivered to the selected site of the spinal cord bilaterally, and along the entire segment. The distance between tracts along the segment will be approximately 1 – 3 mm. Effort should be made to evenly space the bilateral distance between injection tracts. The exact number of injections will be dependent on the segment of the cord being transplanted because of the variation in the size of segments along the spinal cord.
5. The cells must be injected slowly into the spinal cord to avoid cells being forced back along the needle tract and out of the target site. The volume of cells to be injected at each site is a maximum of 20 microliters, which is equal to 2 million cells. Once the target site is selected, the needle is inserted approximately 3 – 7 mm deep into the spinal cord targeting the ventral horn gray matter. Cells are to be injected at a rate of approximately 4 µl per minute until 10–20 µl cells are injected.
6. After the final injection of cells at a target site, the needle/syringe will be held in place for 2-5 minutes. This wait period will allow the cells and injection solution to equilibrate with surrounding tissue to minimize the chance of leakage of cells along the needle tract.
7. Remove the needle / syringe from spinal cord.

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Revision: 00
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Patient Number: CLO-02

Date: 5/16/01

Received on: 5/16/01

Product Lot Number: SCIR006

Time of Arrival of Cells: 5:00 PM

1. The site of damage within the spinal cord will be localized by MRI. A laminectomy will be performed at a location one segment above or below the site of damage. With the spinal cord revealed, the dura will be opened and a needle inserted into the spinal cord to deliver the cells.

NOTE: All draws of fluid must be done very slowly to prevent bubble formation.

2. Gently resuspend (do not shake) the cells for transplant (which have collected into a pellet) by repetitively rotating the vial 90° to the right and to the left until the pellet of cells has dislodged and a uniformly cloudy suspension is achieved.
3. Place the tip of the needle in the cryovial containing the cell suspension for transplant and draw up a maximum of 20 µl.
4. Cells will be delivered to the selected site of the spinal cord bilaterally, and along the entire segment. The distance between tracts along the segment will be approximately 1 – 3 mm. Effort should be made to evenly space the bilateral distance between injection tracts. The exact number of injections will be dependent on the segment of the cord being transplanted because of the variation in the size of segments along the spinal cord.
5. The cells must be injected slowly into the spinal cord to avoid cells being forced back along the needle tract and out of the target site. The volume of cells to be injected at each site is a maximum of 20 microliters, which is equal to 2 million cells. Once the target site is selected, the needle is inserted approximately 3 – 7 mm deep into the spinal cord targeting the ventral horn gray matter. Cells are to be injected at a rate of approximately 4 µl per minute until 10–20 µl cells are injected.
6. After the final injection of cells at a target site, the needle/syringe will be held in place for 2-5 minutes. This wait period will allow the cells and injection solution to equilibrate with surrounding tissue to minimize the chance of leakage of cells along the needle tract.
7. Remove the needle / syringe from spinal cord.

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- Number of deposits

9. Repeat steps for each of the remaining injection tracts.

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Revision: 00
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Cell Number: CCD-01
Patient Number: CCD-01

Date: 4-13-01

Received on: 4-13-01

Product Lot Number: SCIR-005

Time of Arrival of Cells: 7:00 AM

1. The site of damage within the spinal cord will be localized by MRI. A laminectomy will be performed at a location one segment above or below the site of damage. With the spinal cord revealed, the dura will be opened and a needle inserted into the spinal cord to deliver the cells.

DTE: All draws of fluid must be done very slowly to prevent bubble formation.

2. Gently resuspend (do not shake) the cells for transplant (which have collected into a pellet) by repetitively rotating the vial 90° to the right and to the left until the pellet of cells has dislodged and a uniformly cloudy suspension is achieved.
3. Place the tip of the needle in the cryovial containing the cell suspension for transplant and draw up a maximum of 20 µl.
4. Cells will be delivered to the selected site of the spinal cord bilaterally, and along the entire segment. The distance between tracts along the segment will be approximately 1 – 3 mm. Effort should be made to evenly space the bilateral distance between injection tracts. The exact number of injections will be dependent on the segment of the cord being transplanted because of the variation in the size of segments along the spinal cord.
5. The cells must be injected slowly into the spinal cord to avoid cells being forced back along the needle tract and out of the target site. The volume of cells to be injected at each site is a maximum of 20 microliters, which is equal to 2 million cells. Once the target site is selected, the needle is inserted approximately 3 – 7 mm deep into the spinal cord targeting the ventral horn gray matter. Cells are to be injected at a rate of approximately 4 µl per minute until 10–20 µl cells are injected.
6. After the final injection of cells at a target site, the needle/syringe will be held in place for 2-5 minutes. This wait period will allow the cells and injection solution to equilibrate with surrounding tissue to minimize the chance of leakage of cells along the needle tract.
7. Remove the needle / syringe from spinal cord.

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- Distance between deposits
- Number of deposits

9. Repeat steps for each of the remaining injection tracts.

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